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Red Cross Fine Highlights Its Troubled History of Blood Services

http://www.truthdig.com/report/item/10_million_fine_on_red_cross_highlights_its_troubled_history_of_blood_servi/

Posted on Feb 2, 2012

By Lena Groeger, ProPublica

A few weeks ago, the Food and Drug Administration hit the American Red Cross with a nearly $10 million fine for safety violations, lax oversight and faulty testing of its blood services. The fine is just the latest of more than a dozen the Red Cross has racked up in the last decade.

In 2003, a federal court, frustrated by repeated blood safety violations by the Red Cross, gave the FDA the power to fine the organization. Forty-six million dollars in penalties later, many of the same violations—understaffing, ineffective screening of donors, failure to recall infected blood—are outlined in the recent letter the FDA sent to the executive vice president of Biomedical Services for the Red Cross.

The 32-page letter describes hundreds of violations over several months in 2010 at 16 Red Cross facilities across the country, and details how the Red Cross repeatedly failed to properly track and record information about donors and blood units. (To see the actual document and others like it, go to our timeline of Red Cross fines.)

For example, the agency failed to notify health departments when donors had infectious diseases such as HIV and syphilis, failed to add new donors with infected blood to a national list of people who aren't allowed to donate, and failed to review records of donors who had bad reactions, such as a 16-year-old who lost consciousness and fell to the floor after giving a unit of blood. It also failed to follow written procedures, such as the case of a phlebotomist in Arizona who stuck herself with a needle before sticking a donor with the same needle to draw blood. The case went unreported for a month, because a staff member "was not aware of the need to immediately notify a Medical Director," according to the inspection letter.

In a recent statement, the Red Cross said it was disappointed that the FDA issued the fine for "an inspection conducted so long ago" and noted that it has "already taken corrective steps to address those matters and that improvements in operations have been made."

In an email to ProPublica, a Red Cross spokeswoman also said there is no evidence that these violations endangered any patients, adding that the blood supply is safer than it has ever been. The spokeswoman said the agency has made significant improvements, including reducing the number of problems system-wide by at least 65 percent, and is investing in technology upgrades. For example, the agency recently upgraded software and computer equipment at blood drives to better collect and track donor information.

The FDA's letter laying out the fines says the Red Cross "has known of these continuing problems and has failed to take adequate steps to correct them." The FDA also noted that "many of the violations recounted in this letter are virtually identical to violations charged in previous [letters]." In June 2010 the FDA imposed a $16 million penalty on the Red Cross for the same type of violations.

The chronic problems raise the question of whether penalties are working at all.

The Red Cross has been making promises and failing to keep them for over a decade, according to Sidney Wolfe, who heads the health research group at the consumer watchdog organization Public Citizen. Wolfe said he wrote to head of the FDA in 2000, urging it to hold the Red Cross in contempt of court. A federal court first put the Red Cross under government supervision in 1993 after finding blood safety lapses. A decade later, in 2003, the court empowered the FDA to impose fines.

"But fast-forward nine years ahead, and we have the same violations," Wolfe said.

If the Red Cross disagrees with an assessment, it can ask the FDA to reevaluate the penalty, but in most cases the fine only changes by a few thousand dollars.

Most of the recent problems inspectors cited have to do with managing records and tracking blood donors. The Red Cross says it is unaware of any infections or deaths that stemmed from problems noted in the report, and that "serious problems" account for only three percent of the total problems found.

The FDA doesn't think that's good enough.

"FDA cannot definitively say there was never any danger to the blood supply since the violations can create conditions that could lead to potential safety consequences," said FDA spokeswoman Patricia El-Hinnawy.

The government requires that the Red Cross (like any blood services operation) have multiple safeguards for its blood services. That includes asking a donor questions to identify any risks, checking his or her name against a national list of people who aren't allowed to give blood, testing for infectious diseases, keeping track of blood units so infected blood isn't released, and investigating any deviations from standards.

Because blood transfusions always carry a degree of risk, the FDA considers every step in that process critical to minimizing problems. "Failure of an individual safeguard does not automatically translate into the release of unsafe products," an FDA spokeswoman told ProPublica in an email, "however, it may increase the potential for risk."

In 2008, the Red Cross consolidated its blood work to two facilities: one in Charlotte, N.C., and the other in Philadelphia. The offices are in charge of managing, tracking and, if need be, recalling blood. But according to the inspection letter, both offices have been chronically understaffed, and simply haven't been able to carry out their required functions in a timely or effective manner. As of 2010, the offices had a backlog of about 18,000 donor management cases.

Bloomberg Businessweek

News From Bloomberg

American Red Cross Fined $9.6 Million Over Blood Safety

By Molly Peterson on January 18, 2012
http://www.businessweek.com/news/2012-01-18/american-red-cross-fined-9-6-million-over-blood-safety.html

(Updates with comment from Red Cross in fifth paragraph.)

Jan. 13 (Bloomberg) -- The American Red Cross, the biggest U.S. supplier of donated blood, was fined $9.59 million after the Food and Drug Administration found that 16 of its facilities failed to comply with blood-safety rules.

FDA inspectors found "significant violations" from April 2010 to October 2010, including inadequate "managerial control," record-keeping and quality assurance, the agency said today in a letter to the Washington-based organization.

The FDA didn't find any evidence that the lapses led to serious health consequences for blood recipients, said Mary Malarkey, head of compliance at the agency's Center for Biologics Evaluation and Research.

"The safety of the nation's blood supply is one of our top priorities, and we have no reason to believe that it has been compromised in any way," Malarkey said today in a telephone interview. "It's very important to note that people who need transfusions should continue to take their doctors' advice, and we encourage people to donate blood."

The FDA has been working "very closely" with Red Cross management "for quite some time now," Malarkey said. "These are not current violations, and we remain hopeful that their current management team will be able to deal with the situation."

'Corrective Steps'

The fines issued today are "primarily centered on an inspection conducted 15 months ago" at the organization's Donor & Client Support Center in Philadelphia, the Red Cross said today in an e-mailed statement.

"We are disappointed that the FDA believed it necessary to issue a fine for an inspection conducted so long ago and it is important to know we have already taken corrective steps to address those matters and that improvements in operations have been made," the Red Cross said.

The organization said it is "fully committed to meeting all FDA standards, has made significant progress in working with the FDA to comply with their regulations and requirements, and continues to work on improving its performance."

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June 17, 2010

Red Cross Fined Again Over Screening

By THE ASSOCIATED PRESS

Federal health regulators are fining the American Red Cross $16 million for sloppy screening of donated blood, the latest in a series of violations that have cost the group millions of dollars. The Food and Drug Administration says the group failed to take precautions to assure the safety of blood donations. Despite those oversights, the F.D.A. says the United States blood supply appears to be safe. The F.D.A. has cited the Red Cross a dozen times already and fined the organization more than $21 million since 2003.

The New York Times

Despite Fines and Promises, Red Cross Falters With Blood; [National Desk]

Stephanie Strom. **New York Times**. (Late Edition (East Coast)). New York, N.Y.: Jul 17, 2008. pg. A.1

Abstract (Summary)

The situation has proved so frustrating that in January the commissioner of food and drugs attended a Red Cross board meeting -- a first for a commissioner -- and warned members that they could face criminal charges for their continued failure to bring about compliance, according to three Red Cross officials who attended the meeting and requested anonymity because Red Cross policy prohibits public discussion of its meetings with regulators.

Full Text (2541 words)

For 15 years, the American Red Cross has been under a federal court order to improve the way it collects and processes blood. Yet, despite $21 million in fines since 2003 and repeated promises to follow procedures intended to ensure the safety of the nation's blood supply, it continues to fall short.

The situation has proved so frustrating that in January the commissioner of food and drugs attended a Red Cross board meeting -- a first for a commissioner -- and warned members that they could face criminal charges for their continued failure to bring about compliance, according to three Red Cross officials who attended the meeting and requested anonymity because Red Cross policy prohibits public discussion of its meetings with regulators.

"If fear is a motivator, we're happy to help out in that way," said Eric M. Blumberg, deputy general counsel at the Food and Drug Administration, though he declined to confirm what the commissioner, Andrew C. von Eschenbach, said at the meeting.

Some critics, including former Red Cross executives, have even suggested breaking off the blood services operations from the rest of the organization, as the Canadian Red Cross did a decade ago.

The problems, described in more than a dozen publicly available F.D.A. reports -- some of which cite hundreds of lapses -- include shortcomings in screening donors for possible exposure to diseases; failures to spend enough time swabbing arms before inserting needles; failures to test for syphilis; and failures to discard deficient blood.

In some cases, the lapses have put the recipients of blood at risk for diseases like hepatitis, malaria and syphilis. But according to the food and drug agency, the Red Cross has repeatedly failed to investigate the results of its mistakes, meaning there is no reliable record of whether recipients were harmed by the blood it collected.

The Red Cross, which controls 43 percent of the nation's blood supply, agrees that it has had quality-control problems and is working to fix them. Both its officials and the drug agency point out that none of the identified problems involve the most serious category of infractions. For instance, the Red Cross does a good job of testing for H.I.V. and hepatitis B, officials on all sides agree. And in general, Red Cross blood is regarded as some of the safest in the world.

Still, the drug agency says, the problems that remain in screening donors and following protocols for collection add unnecessary risk to blood transfusions, almost five million of which were done in 2007, according to the National Heart, Lung and Blood Institute.

"This is a critical piece of the public health infrastructure," Mary A. Malarkey, director of the Office of Compliance and Biologics Quality at the drug agency, said in an interview. "I know it's difficult to get so many people trained and properly supervised, but it has to be done."

This week, the agency sent the Red Cross the results of yet another recent investigation that makes Ms. Malarkey's point: From December 2006 to April 2008, the Red Cross distributed more than 200 blood products that it had already identified as problematic, according to the investigation report.

A Troubled History

While many Americans see the Red Cross as the ubiquitous organization that responds to disasters big and small, its disaster-relief operation, which spends $400 million to $500 million annually, is small compared with its blood business, which generated $2.1 billion in revenue in the fiscal year that ended in June 2007.

In fact, the Red Cross is the world's largest single steward of blood, more than twice the size of the second-largest known blood collection operation. The rest of the world's blood supply is controlled by dozens of smaller organizations, only three of which have ever been under F.D.A.-requested consent decree.

After years of quiet complaints about the Red Cross's blood business, the F.D.A. reluctantly decided to go public with its concerns in 1993, obtaining a consent decree that required the Red Cross to strengthen quality control and training and improve its ability to identify, investigate and record problems.

The Washington Post

WASHINGTON IN BRIEF

Thursday, February 7, 2008; A04

FDA Fines Red Cross $4.6 Million

The American Red Cross, the biggest operator of U.S. blood banks, was fined $4.6 million after regulators found that it failed to properly screen blood donations.

The Food and Drug Administration sent a letter to the Red Cross yesterday describing the agency's findings, said FDA spokeswoman Peper Long. The penalty followed an FDA review of blood that was recalled by the Red Cross, she said.

Regulators have fined the Red Cross more than $20 million since the FDA and Red Cross entered into a legal agreement in 2003 allowing penalties for failing to follow federal standards to ensure blood is not contaminated, Long said.

There is no indication patients were harmed by the failures associated with the fine, the FDA said.

Regulators identified 113 blood recalls from 2003 to 2006 that could have been prevented if the Red Cross, based in the District, had followed procedures. The Red Cross did not perform required tests on the blood and failed to ask donors questions to determine their eligibility, Long said.

The Red Cross is reviewing the FDA letter and has taken steps to improve compliance with the rules, said Eva Quinley, senior vice president of quality and regulatory affairs for blood.

Jefferson Charges to Remain